

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Eric C. Miller et al.

Confirmation No.: 4511

Application No.: 09/972,342

Group Art Unit: 2615

Filed: October 6, 2001

Examiner: Con P. Tran

For: INFORMATION SYSTEM USING
EYEWEAR FOR COMMUNICATION

Attorney Docket No.: 90747-4600

RULE 132 DECLARATION

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Sir:

I, Barry Kauker, currently residing at 3500 Via Flores, Soquel CA 95073
hereby declare that:

1. I am a Principal Engineer with Stryker Endoscopy and have over 22 years experience in the Medical Device Product Development field. I am the named inventor on 9 Patents covering a variety of products used daily in the operating room and have other patents pending. I consider myself to be one of ordinary skill in the art of product development and qualified to comment on the merits of the above-identified patent application.

2. I understand that the claims of this invention are directed to improvements in protective eyewear that includes a communication system built into the eyewear and the provision of the ability to clearly hear environmental audio inputs. One particularly important use of the invention is in a surgical operating room where much of the wearer's lower face is typically covered by a surgical mask and much of the head is covered by a surgical cap. The claimed eyewear comprises a microphone, a speaker, and an eyewear neck strap that couples the microphone and speaker to a wearer unit carried by the eyewear wearer. The wearer unit exchanges wireless signals with a base station. The base station is coupled to various devices

such as surgical theater equipment, and/or to a telecommunication system, such as a telephone system. The eyewear enables the wearer to conduct hands-free communication such as telephone conversations and command and control operations. The eyewear is also configured such that speaker is held away from the wearer's ear so that a gap exists between speaker and the wearer's external outer ear. This gap is made large enough so that external sound is not obstructed from reaching the wearer's ear canal. Thus, an advantage of the presently claimed invention is that it allows a surgeon, for example, to conduct command and control operation via the speaker and microphone, and at the same time hear the surrounding environment of a surgical operating room.

3. In an operating room it is absolutely critical that the surgeon be completely aware of what is going on around him or her at all times. Configuring a speaker system with an air gap allows the surgeon to clearly hear what is going on within the operating room while at the same time getting the information he needs through the speaker system attached to his protective eyewear. Any obstruction of external sounds such as equipment warnings or instructions from his assistance would put the patient in danger. To clearly hear output from the speaker system, the speaker mount must be properly positioned away from the ear but sufficiently close so as cause no distraction to others nearby. The present invention solves the concerns of audible obstruction and speaker placement and makes the operating room a safer place to perform surgery.

4. Although a large housing or a boom could have been used to position the microphone close to the wearer's mouth, medical personnel, especially surgeons, prefer to keep as much equipment as possible away from their face and away from the mask and cap. If a boom is used, the microphone position can be altered if the boom is displaced when removed from the wearer's head. A boom can snag on other objects. Thus an advantage of the integral microphone housing of the present invention is that the wearer is unaware of the presence of the microphone. The microphone remains in the correct position during use as well as during eyeglasses use and storage, and no microphone position readjustment is required.

5. I have reviewed the office action dated March 30, 2007, and understand that the claims 28-29, and 32 have been rejected over the combination of US patent 3,807,526 to

Sygnator and US patent 5,327,178 to McManigal, claims 30-31, 33-35, 37, and 39 have been rejected over the combination of Sygnator, McManigal, and US patent 6,176,576 to Green, claims 38, and 40-45 have been rejected over the combination of Sygnator, McManigal, and US patent 6,091,546 to Spitzer, and claim 36 has been rejected over the combination of Sygnator, McManigal, Green, and US patent 3,781,492 to Cragg. I respectfully disagree with these rejections.

6. Sygnator is directed to an ear protection device in which the ear protector is attached to a temple bar covering the ear and reducing the high decibel noise levels such as constant and recurring sounds encountered in industrial operations from punch presses, riveting operations and many others. Sygnator's device uses a pad that completely blocks the wearer's ear to block sounds from entering so as to protect the person's hearing. It is important to note that this is necessary in Sygnator because the sound intensity of industrial equipment, such as a punch press, can be as high as 112 dB, while acceptable sound intensity for an eight hour period is 85 dB (see, <http://www.phppo.cdc.gov/niosh/docs/2004-101/pdfs/Safe.pdf> , page83; http://www.cdc.gov/niosh/topics/noise/about/hlp/noisemeter_flash/soundMeter_flash.html). An effective protection device such as that taught by Sygnator needs to reduce the sound level from 112 dB to about 85 dB, a reduction of 27 dB or approximately a 22 times reduction in loudness. Further, the intensity level of a normal conversation is 60 dB, a significantly different level from the punch press intensity (approximately 1/400 times the loudness level of a punch press). A passive device, such as Sygnator, designed to address the high decibel noise levels occurring in the industrial operations, cannot effectively function as a protective device and at the same time permit the wearer to hear environmental sounds without significant obstruction, as any reduction applied to high decibel levels would also be applicable to environmental sounds. It is clear that a 22 times reduction in loudness of normal conversation level, cited in the above example, is a significant reduction.

7. The Office Action argues that Sygnator's device permits the wearer to hear environment sounds without significant obstruction by citing an entirely separate embodiment from the embodiment that is used for the analogy to the independent claims of the present invention. It is important to note that these two embodiments are mutually exclusive. The embodiment used for the analogy includes a pad "that is intended to overlie a larger area of the

concha", while the other embodiment does not include a pad, and as such, the performs of these two embodiments significantly differs. The embodiment with a pad "will have a correspondingly greater barrier effect as perhaps comparable to placing the palm of one's hand over the ear rather loosely" (*see* col. 2, lines 56-59). As mentioned above, in an OR it is absolutely critical that the surgeon is completely aware of what is going on around him or her at all times, and thus, having the surgeon's ear covered as if by placing the palm of one's hand over the ear, even rather loosely, is entirely unacceptable, as such configuration would most certainly compromise communications and possibly endanger the life of the patient. Thus, in my view as a person of ordinary skill in the art, Sygnator does not disclose, teach or suggest the presently claimed invention.

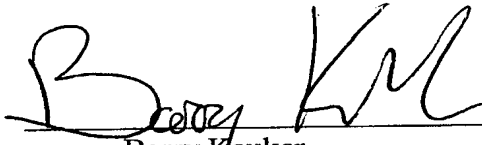
8. McManigal intends to provide the individual quality sound from a personal audio source, without speakers touching the ears, and/or without interfering and blocking surrounding sounds from the environment. Sygnator's teaching of preventing or blocking the hearing of ambient sounds is completely contradictory to McManigal's teaching. As discussed above the Sygnator's device would equally reduce both the high decibel sounds and other environmental sound, thus, a skilled artisan, well aware of this fact, would not attempt to combine these teachings since any advantage provided by one teaching would be at the cost of the other teaching. This inconsistent approach is illogical and does not support the rejection.

9. The present invention also has many other commercial applications where there is a desire for a communication system built into protective eyewear with the need to clearly hear environmental audio inputs. For example, sunglasses with these features could be safely worn while driving a car or riding a bike-allowing communication to occur while still allowing monitoring of environment sounds relating to traffic, emergency vehicles, verbal warnings or the like.

10. I have also reviewed the Spitzer, Green and Cragg references and find that they do not provide any disclosure that would remedy the deficiencies of the Sygnator and McManigal references to render the present claims obvious.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, and any patent issuing thereon.

Date: 7/5/07



Barry Kauker